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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,449	12/13/2005	James Edward Eyles	41577/317929	5114
23370	7590	12/12/2007		
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			12/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,449	<b>Applicant(s)</b> EYLES ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 1 October 2007, is acknowledged.  
Claims 1-15 have been cancelled. Claim 17 has been amended. New claims 18-27 have been added.
2. Claims 17-27 are pending and under consideration.

### **Rejections/Objections Withdrawn/Moot**

3. The objection to Figure 2 is withdrawn in light of the replacement drawing submitted.
4. The objection to Figure 3 is withdrawn in light of the replacement drawing submitted.
5. The objection to claim 2 for "sequences" is moot in light of the cancelation of the claim.
6. The objection to claim 10 for "lyophilised" is moot in light of the cancelation of the claim.
7. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for "free reagent to the reagent associated with the microspheres" is moot in light of the cancelation of the claim.
8. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for "associated", is moot in light of the cancelation of the claim.
9. The rejection of claims 1-14 under 35 U.S.C. 102(b) as being anticipated by Eyles et al (*Vaccine*, 19:4732-4742, 2001) is moot in light of the cancelation of the claims.
10. The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Eyles et al (*Vaccine*, 19:4732-4742, 2001) in view of Britto et al (U.S. Pat. No. 6,098,619, 8Aug2000) is moot in light of the cancelation of the claim.

11. The rejection of claim 17 under 35 U.S.C. 102(b) as being anticipated by Eyles et al (*Vaccine*, 19:4732-4742, 2001) is withdrawn in light of the amendment of the claim and applicants' argument.

**Claim Rejections - 35 USC § 112**

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 17-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is drawn to a method of producing a protective immune response in a mammal in need thereof by administration to a lung of the mammal, a protective amount of an aerosol comprising microspheres comprising a nonliving reagent that produces a protective immune response in a mammal to whom it is administered.

Claims 18-21 are dependent claims which identify the nonliving reagent. Claims 17-25 are dependent claims which identify the make-up of the microspheres. Claims 26-27 are drawn to relationships between the microspheres and the nonliving reagent.

While the claims do designate the nonliving reagent and the microspheres, none of the claims are drawn to any particular designation of "a protective immune response in a mammal in need thereof" or any nexus between the elicited "protective immune response" and the response to the nonliving reagent. Thus, it is unclear how what is being claimed. For instance, are the claims drawn to producing a protective immune response against pneumococcal infection by administration of an aerosol comprising microspheres and a peptide obtained from *B. anthracis*?

14. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what how the claim further limits the invention of claim 17. Claim 17 is drawn to a method wherein the microspheres "comprise" the nonliving reagent. Depend claim 26 recites that the nonliving reagent is encapsulated within the microspheres.

### **Conclusion**

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10/542,449  
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RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

December 9, 2007